

MAR - 9 2004

## 510(k) Summary of Safety & Effectiveness

(as required by 21 CFR 807.92c)

**Date Prepared:**

Dec 18, 2003

**Submitter's Information:**

Sectra Imtec AB

Teknikringen 20

SE-583 30 Linköping

Sweden

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**Trade Name, Common Name, Classification:**

Trade name: Sectra Angiography and Cardiology Package

Common Names: Picture Archiving and Communications System

Classification Name: Image Processing System (LLZ) (21 CFR § 892.2050)

**Predicate Devices:**

Applicant: Medical Imaging Systems (MEDIS)

510(k) Number: K993761

Device: QCA-View (Cardiovascular Measurement System – View)

Applicant: Medical Imaging Systems

510(k) Number: K993763

Device: QCA-CMS (Quantitative Analysis of Coronary Angiograms)

Applicant: Medical Imaging Systems (MEDIS)

510(k) Number: K993765

Device: QLV-CMS (Quantitative Analysis of Left Ventricular Angiograms)

Applicant: Medical Imaging Systems (MEDIS)

510(k) Number: K023970

Device: QVA-CMS (QVA-CMS Analytical software package)

**Device Description:**

Sectra Angiography and Cardiology Package is intended to support radiologists and cardiologists in the diagnostic process to quantify findings. The device has functionality for quantitative analysis of the arteriograms (QCA and QVA) and quantitative analysis of the left ventricular angiographic images (LVA). Measurements can be applied on angiographic images.

**Indications for Use:**

The Sectra Angiography and Cardiology Package provides quantitative and reproducible information regarding the calculated dimensions of arterial segments, and quantitative information regarding the calculated dimensions and calculated performance characteristics of the left ventricle of the heart, imaged during angiographic x-ray procedures typically performed in cath labs.

This information is suitable for use in the following applications:

1. Scientific and research studies, assessing the angiographic condition of patients and the result of device and drug therapeutics,
2. Review and analysis of patient angiographic imaging records, providing additional information to physicians and administrators.

Typical users of the device are trained professionals, e.g. physicians, radiologists, cardiologists and scientists.

**Technological Characteristics:**

The Sectra Angiography and Cardiology Package will run on the Windows 2000, and Windows XP operating systems for PCs (as a minimum and depending upon system configuration) featuring a Sectra IDS5 Radiology Workstation.

**Performance Data:**

The subject device is developed according to ISO 9001:2000 and complies with ACR/NEMA Digital Imaging Communications in Medicine version 3.0.

**Conclusion:**

Similar to the predicate devices, the Sectra Angiography and Cardiology Package does not contact the patient, nor does it control any life sustaining devices. Images and information being reviewed, processed, relayed, and or transmitted are interpreted by a trained professional, e.g. radiologist, cardiologist, providing ample opportunity for competent human intervention. Device failures, which might result in partial or failed transmissions, images, or data, may be recovered from storage or re-transmission after correcting the problem(s). Passwords are required for operation and to protect against unauthorized use.

Based on the information supplied in this 510(k), we conclude that the subject device is safe, effective, and substantially equivalent to the predicate devices.



Peter Andersson  
Regulatory Affairs Officer  
Sectra Imtec AB  
Teknikringen 20  
SE-58330 Linköping  
Sweden



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR - 9 2004

Sectra Imtec AB  
% Mr. Carl Alletto  
United States Agent  
OTech, Inc.  
1100 Lakeview Blvd.  
DENTON TX 76208

Re: K034059

Trade/Device Name: Sectra Angiography and  
Cardiology Package

Regulation Number: 21 CFR 892.2050

Regulation Name: Picture archiving and  
communications system

Regulatory Class: II

Product Code: 90 LLZ

Dated: December 22, 2003

Received: December 31, 2003

Dear Mr. Alletto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

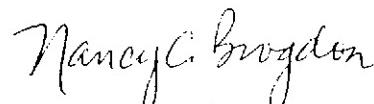
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

510(k) Number: K034059

Device Name: Sectra Angiography and Cardiology Package

Indications For Use:

The Sectra Angiography and Cardiology Package provides quantitative and reproducible information regarding the calculated dimensions of arterial segments, and quantitative information regarding the calculated dimensions and calculated performance characteristics of the left ventricle of the heart, imaged during angiographic x-ray procedures typically performed in cath labs.

This information is suitable for use in the following applications:

1. Scientific and research studies, assessing the angiographic condition of patients and the result of device and drug therapeutics,
2. Review and analysis of patient angiographic imaging records, providing additional information to physicians and administrators.

Typical users of the device are trained professionals, e.g. physicians, radiologists, cardiologists and scientists.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)

Nancy C. Brogdon  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K034059